IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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SANOFI-AVENTIS U.S. LLC, SANOFI-AVENTIS, DEBIOPHARM S.A., Plaintiffs, v. SANDOZ, INC. *et al.* Defendants.	CIVIL ACTION NO.: 3:07-cv-02762-JAP-DEA (consolidated) **FILED UNDER SEAL** **HIGHLY CONFIDENTIAL INFORMATION - OUTSIDE COUNSEL ONLY**

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION FOR A PRELIMINARY INJUNCTION AGAINST SUN

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INTRODUCTION

On February 14, 2011, the Federal Circuit mandate issued, vacating this Court's April 2010 injunction against Sun and allowing Sun to launch its generic oxaliplatin product without notice and at a time of its own choosing.[1] If Sun were to launch before this Court decides the meaning of "decision(s) enjoining" as the Federal Circuit instructed,

Plaintiffs requested that Sun refrain from launching its generic product until this Court resolves that single remaining issue in the case. In response, Sun made impractical and shifting demands of plaintiffs that involve complicated commercial arrangements going far beyond a simple standstill agreement to refrain from selling until this Court has considered the merits of the parties' contract dispute. Plaintiffs went to great lengths in their efforts to reach a standstill agreement, including sending a senior Sanofi business representative to India for face-to-face discussions. However, no agreement was reached, and plaintiffs have filed this motion for a preliminary injunction to maintain the status quo and avoid the inevitable and severe irreparable harm that would result if Sun launches its generic product prior to the resolution of this action.

The purpose of a preliminary injunction is "to preserve the relative positions of the parties until a trial on the merits can be held." *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1345 (Fed. Cir. 2008). A preliminary injunction should issue here because, as shown below, plaintiffs have demonstrated that all four preliminary injunction factors weigh heavily in favor of the grant of that relief.

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[1] By agreement between the parties, Sun cannot launch its product until February 17, 2011. (D.I. 696). "D.I." numbers refer to entries on the consolidated docket, case no. 3:07-cv-02762.

First, plaintiffs will likely succeed on the merits of the sole remaining issue in this case. The evidence points to only one reasonable conclusion -- "decision(s) enjoining" as used in the Sun License means any judicial act which results in an injunction, ***not*** decisions on the merits, as Sun contends.

The context of the Sun License compels the conclusion that "decision(s) enjoining" encompasses any judicial act -- including consent judgments -- enjoining defendants other than Sun from selling generic oxaliplatin. Plaintiffs and Sun understood that

In its license, Sun received a royalty-free license allowing it to sell generic oxaliplatin more than one year before plaintiffs' ELOXATIN® exclusivity ends, *i.e.*, on August 9, 2012. As part of that license, Sun bargained for and received contingent rights designed to protect Sun if other defendants were to launch their competitive products prior to August 9, 2012, namely, rights to accelerate the date when Sun could sell generic product. Among other acceleration rights, Sun received the option to sell its generic product if any non-settling defendant were to sell generic product at risk prior to August 9, 2012.

Plaintiffs could agree to grant Sun this substantial benefit only if they were protected in the scenario where the at-risk defendants were later enjoined from continuing to sell generic product. That protection meant that if all of the at-risk sellers were enjoined, Sun would also have to cease selling its generic product -- otherwise, Sanofi would not regain the ELOXATIN® exclusivity it had bargained for consistent with the scope of the patent at issue, and the injunctions against those other defendants would serve no meaningful purpose. Thus, in exchange for granting Sun the option to join the other defendants' at risk launch, plaintiffs insisted that Sun agree to cease selling its product if the other at-risk sellers were enjoined. There was no conceivable reason for plaintiffs to grant Sun the option to sell at-risk without the corresponding obligation that Sun cease selling if the other generic at-risk sellers were enjoined.

Sun's argument that "decision(s)" must be limited as a matter of law to decisions on the merits is contrary to precedent. Case law clearly recognizes that consent judgments are "decision(s)" of the court. Sun's cases are inapposite because they address only "decisions on the merits," which is not the language used in the Sun License.

As for the extrinsic evidence, it fully supports plaintiffs' position in this case. In fact, as explained below, changes made to the terms of the parties' preliminary term sheet to reach the final Sun License show that Sun understood that "decision(s) enjoining" are not limited to "decisions on the merits."

Second, the irreparable harm plaintiffs will suffer overwhelmingly supports the grant of preliminary injunctive relief.

Third, as for the balance of hardships, in contrast to the devastating harms to plaintiffs here, Sun has virtually nothing to lose from a brief delay of the product launch that

would result in the unlikely event that it succeeds on the merits. Sun's generic oxaliplatin product is the heavily disfavored lyophilized (freeze dried) product, which in the earlier generic launch achieved minimal sales. In any prospective launch, Sun's product will fare no better because the vast majority of sales will go to the highly favored ready to use oxaliplatin solution product sold by Sun's competitors. Sun would be competing against larger generic competitors (*e.g.*, Teva), having superior products, and, as explained below, Sun will capture even fewer sales than in the first generic launch.

The parties have agreed to expedite discovery, which is scheduled to be completed by early March 2011, and will request a hearing as soon as possible thereafter. Given the competitive landscape, Sun, it cannot legitimately claim it will be harmed by the short delay needed to resolve the remaining issue in this case.

Finally, the public interest, which benefits from enforcement of valid contracts, favors the grant of preliminary relief here.

BACKGROUND

On April 22, 2010, pursuant to the settlement of plaintiffs' oxaliplatin patent infringement case against Sun, this Court entered a Consent Judgment and Order, which enjoined Sun's sales of generic oxaliplatin from June 30, 2010 until August 9, 2012. (D.I. 661). Sun appealed, asserting that this Consent Judgment was improperly entered. On December 22, 2010, the Federal Circuit issued a decision vacating the injunction against Sun. *Sanofi-Aventis v. Sandoz*, No. 2010-1338, slip op. (Fed. Cir. Dec. 22, 2010) ("Fed. Cir. Dec.") (Gupta Decl. Ex.

1).[2] That Court concluded that the meaning of the phrase "decision(s) enjoining" used in the parties' settlement documents was ambiguous, and instructed this Court to allow the parties to "conduct discovery and present their evidence as to the proper resolution of the ambiguous language in the license agreement." (*Id.* at 15).

The Federal Circuit's mandate, which serves to vacate the existing injunction against Sun, issued on February 14, 2011. As further explained below, if Sun launches its generic oxaliplatin product,

The only remaining issue in this case is whether the consent judgments entered against defendants other than Sun are "decision(s) enjoining" within the meaning of the Sun License Agreement. Plaintiffs have asked Sun to agree not to launch its generic product prior to the resolution of this sole remaining issue. Sun refused, necessitating this motion.[3]

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[2] In support of this motion, plaintiffs submit the declarations of Vishal C. Gupta, Esq. ("Gupta Decl."), Sanofi's associate general counsel, Martin Travers ("Travers Decl."), Sanofi's head of the U.S. Oncology Business Unit, Paul Hawthorne ("Hawthorne Decl."), Debiopharm's executive vice president, Thierry Mauvernay ("Mauvernay Decl."), and plaintiffs' economic expert Dr. Henry Grabowski, who has submitted a declaration concerning harm issues ("Grabowski Decl.") and a declaration addressing the amount of an appropriate bond ("Grabowski Bond Decl.").

FACTS

A. The Structure of Each of the Oxaliplatin Settlements

Efforts to settle all of the oxaliplatin patent infringement actions in this Court were initiated in the summer of 2008 pursuant to an order of the Court. (*See* Scheduling Order dated Oct. 23, 2007, D.I. 18 ¶¶ 10-11; Case Management Order dated Apr. 21, 2008, D.I. 33 at 5; Travers Decl. ¶ 5). To facilitate settlement, plaintiffs developed a basic approach or structure for a settlement agreement that could be used to settle the litigations with each of the seven groups of defendants. (Travers Decl. ¶ 5).[4]

[4] Those groups of defendants consist of: (1) Teva Parenteral Medicines, Inc., Teva Pharmaceuticals USA, Inc., Pharmachemie B.V., Barr Laboratories, Inc., PLIVA-Lachema A.S., PLIVA HRVATSKA d.o.o., (2) Fresenius Kabi Oncology, PLC, Fresenius Kabi Oncology Limited, Dabur Oncology PLC, Dabur Pharma Limited, APP Pharmaceuticals LLC, Abraxis Bioscience, Inc., (3) Sandoz, Inc., Ebewe Pharma Ges.m.b.H. Nfg.KG, (4) Actavis Totowa LLC, Actavis, Inc., Actavis Group HF, (5) Mustafa Nevzat Ilac Sanayii A.S., Par Pharmaceutical Companies, Inc., Par Pharmaceutical, Inc., (6) Mayne Pharma Limited, Mayne Pharma (USA) Inc., Hospira, Inc., Hospira Australia Pty Ltd., Hospira Worldwide, Inc., Hospira Worldwide Pty, (7) Sun Pharmaceutical Industries, Ltd., and Caraco Pharmaceutical Laboratories, Ltd.

B. Plaintiffs' Settlement With Sun

Plaintiffs' settlement with Sun includes a non-exclusive, royalty-free license that permits Sun to sell its generic oxaliplatin product on the August 9, 2012 Launch Date. (Travers Decl. Ex. 1 §§ 1.21, 2). Sun's settlement also includes other provisions

(Travers Decl. ¶ 12). Section 3.5 of the Sun License is one such provision, which protects Sun if another defendant launches "at risk," by granting Sun the option to also launch:

> In the event that, during the term of the Licensed Patents and without Sanofi's permission, any defendant in the Consolidated Eloxatin Patent Litigation sells a generic version of a Sanofi NDA Product in the Territory prior to a Final Court Decision ("At-Risk Launch"), ***[Sun] will have the option of selling*** its Generic Equivalent prior to the Launch Date.

[6] An "at-risk" launch may occur when a court in a Hatch-Waxman patent infringement case enters a judgment adverse to the patentee terminating the statutory FDA stay of final approval of the defendants' generic products. (Travers Decl. ¶ 9 n.3).

(Travers Decl. ¶ 12, Ex. 1 § 3.5, emphasis added).

Section 3.5 of the Sun License also provides that if all other defendants who launched "at risk" are subsequently enjoined, Sun also must cease its generic oxaliplatin sales:

> Should Sun exercise such an option and a Court subsequently enters a decision(s) enjoining each such At-Risk Launch product(s), ***Sun agrees that Sun will not sell its Generic Equivalent from the time the Court enters an injunction(s) against each such At-Risk Launch Product(s)*** until the Launch Date.

(*Id.* ¶ 13, Ex. 1, § 3.5) (emphasis added).[7]

Plaintiffs would not have settled with Sun absent the requirement that Sun exit the market upon termination of the "at-risk" launches by other defendants. If all defendants except Sun were enjoined, leaving Sun free to continue its generic sales, settlement with Sun would have no value to plaintiffs, since they would not receive the market exclusivity they bargained for, consistient with the scope of the patent at issue. That is, without this protection, plaintiffs risked losing even more valuable market exclusivity than the 13 month period they had bargained away.

(*Id.* ¶ 14).

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[7] Sun also required additional protections to ensure that it would not be prejudiced in the marketplace by agreeing to forgo sales until the Launch Date. Sun insisted, and plaintiffs agreed, that if another defendant was granted an earlier Launch Date as part of its settlement, Sun's "Launch Date shall automatically be amended to the earliest date such Third Party is permitted to begin marketing its Generic Equivalent." (*Id.*, Ex. 1, § 3.3). Similarly, the Sun License also provides that in the event of a Final Court Decision (as defined in the Sun License) allowing a non-settling defendant to sell generic product prior to August 9, 2012, Sun's "Launch Date shall automatically be amended to the date on which that Court decision becomes final." (*Id.* ¶ 15, Ex. 1, § 3.4).

ARGUMENT

ALL FOUR PRELIMINARY INJUNCTION FACTORS WEIGH HEAVILY IN FAVOR OF THE GRANT OF PRELIMINARY RELIEF

In deciding whether to grant a preliminary injunction, courts weigh the "reasonable likelihood" that the moving party will succeed on the merits, the irreparable harm that will result in the absence of preliminary relief, the balance of hardships, and the public interest. *See Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1363 (Fed. Cir. 2001); *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1374 (Fed. Cir. 2006); *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharm. Co.*, 290 F.3d 578, 586 (3d Cir. 2002); *Arch Pers. Care Prods., L.P. v. Malmstrom*, 90 Fed. Appx. 17, 21 (3d Cir. 2003) (unpublished). As explained below, all four factors here weigh heavily in favor of granting preliminary relief to plaintiffs.

I. Plaintiffs Are Reasonably Likely to Succeed On the Merits

Under the Federal Circuit's remand instructions, the only issue to be decided by this Court is the meaning of the phrase "decision(s) enjoining," as used in Section 3.5 of the Sun License. (Gupta Decl. Ex. 1 at 15). To decide this issue, in addition to the intrinsic evidence found in the parties' contract, this Court may consider relevant extrinsic (parol) evidence. (*Id.*).

This Court should construe "decision(s) enjoining" to encompass any judicial act -- including a consent judgment -- that results in an injunction. As demonstrated below, this meaning is compelled by the plain language of the parties' contract, the contract's purpose and context, and the parol evidence. Moreover, precedent recognizes that the act of rendering a consent judgment constitutes a "decision" of the Court, and that contracting parties ordinarily are bound by the meaning of terms that they use which is established by case law.

Yet, Sun advocates an artificially narrow definition of "decision(s) enjoining," limited to decisions *on the merits*, *i.e.*, after full adjudication of the merits of the case. The evidence fails to support Sun's position, and Sun's own proffered extrinsic evidence discloses that Sun understood that "decision(s) enjoining" is not limited to "decisions on the merits."

A. The Language, Purpose, and Context of the Sun License Compel the Conclusion That "Decision(s) Enjoining" Includes Consent Judgments

Under Section 3.5 of the Sun License (quoted in full at pages 9-10 *supra*), if the Court enters "decision(s) enjoining" the other defendants' "at-risk" sales, "Sun agrees that Sun will not sell its Generic Equivalent from the time the Court enters an injunction(s) against each such At-Risk Launch Product(s) until the Launch Date."

Given its context within Section 3.5, the term "decision(s)" serves to identify the mechanism whereby an injunction comes into being. That is, in context, "decision(s) enjoining" is synonymous with "orders enjoining" or "judgments enjoining."[8] In fact, on appeal, Sun acknowledged that "'decision(s) enjoining' refers to injunction orders" (Gupta Decl. Ex. 3 at 32) -- and indisputably injunction orders have been entered against all of the defendants who launched at risk.

The purpose and context of the Sun License agreement confirm that the parties never intended -- as Sun now contends -- to artificially limit the meaning of "decision(s) enjoining" to include only those injunctions that result from this Court's full adjudication of the merits of plaintiffs' patent infringement case. As explained above, Sun received a non-exclusive, royalty-free license that fixed a date certain prior to termination of ELOXATIN® exclusivity

[8] This conclusion is also supported by the parties' use of the language "***enters*** a decision(s) enjoining" (emphasis added) in Section 3.5, which parallels their use in that section of the language "***enters*** an injunction(s) against each such At-Risk Launch Product(s) . . . ." (Travers Decl. Ex. 1 § 3.5, emphasis added).

when Sun's product launch could begin. To protect Sun, plaintiffs granted Sun a number of contingent acceleration rights, granting Sun the benefit of an earlier launch date if some other defendant were able to launch prior to August 2012. Those rights permitted Sun to sit on the sidelines, and if another defendant either negotiated a better deal, finally prevailed on the merits, or launched at risk, Sun would enjoy those benefits as well, without any burden, expense, or litigation risk. (*See* pages 9-10 *supra*).

In particular, Sun received the right to make pre-Launch Date "at-risk" sales, a benefit well beyond that conferred by the parties' basic agreement. Sun would receive that benefit based solely on the litigation expense and risk assumed by the other defendants who pursued their case against plaintiffs (clearing the way for an at-risk launch). And, Sun was guaranteed to make a substantial profit on any such "at-risk" sales because under the Sun License, no damages would be owed for those sales unless plaintiffs finally succeeded on the merits of their case, and even then, Sun would owe only 60% of its gross profits. (Travers Decl. Ex. 1 § 3.5; *see* page 18 *infra*).

In exchange for these substantial, additional, and risk-free benefits, Sun agreed to leave the market if the other defendants who launched "at-risk" were required by injunction to do so. Plaintiffs could accept nothing less -- without this protection, having already bargained away 13 months of patent exclusivity, plaintiffs risked losing the pre-August 9, 2012 exclusivity period they had obtained (or were bargaining for) in their agreements with other defendants.

Thus, any settlement plaintiffs made could not countenance circumstances where one defendant could sell generic oxaliplatin to the exclusion of the others. (*See* pages 6-10 *supra*).

Thus, Sun's position here is plainly belied by the purpose of the Sun License and the context in which that agreement was made. Sun has no credible basis for the result it seeks here, which fully preserves its own right to join in the other defendants' at-risk launch, while abrogating plaintiffs' right to have Sun exit the market when, by virtue of an injunction order, each of the other defendants is required to do so. Given the context and purpose of the parties' agreement and the substantial benefits that agreement accorded to Sun, there is no basis to interpret the Sun License to require such an incongruous and inequitable result. *See In re Delta Airlines, Inc.*, 608 F.3d 139, 146 (2d Cir. 2010) ("[E]ach word must be considered along with not only all the other words that surround it, but also the history and education of the parties, the nature of the contract, the purposes of the parties, and all other relevant circumstances.") (internal quotations omitted); *Evans v. Famous Music Corp.*, 807 N.E.2d 869 (N.Y. 2004) ("It is well settled that our role in interpreting a contract is to ascertain the intention of the parties at the time they entered into the contract."); *Aron v. Gillman*, 128 N.E.2d 284, 288 (N.Y. 1955) ("It is well settled that in construing the provisions of a contract we should give due consideration to the circumstances surrounding its execution, to the purpose of the parties in making the contract, and, if possible, we should give to the agreement a fair and reasonable interpretation.").[9]

B. Courts Recognize That Consent Judgments Are Judicial Decisions

Many courts have recognized that the act of rendering a consent judgment constitutes a decision of the court. For example, in *United States v. City of Miami*, a case on which Sun placed principal reliance on appeal, the court recognized that consent judgments do

[9] The parties agreed in the Sun License that New York law controls interpretation of that contract. (Travers Decl. Ex. 1 § 10.6).

not result from a mere rubber stamp on the parties' contract, but are judicial functions that require scrutiny and careful consideration:

> [A consent] judgment is ***not an inter partes contract***; the court is not properly a recorder of contracts, but is an organ of government constituted to make judicial decisions and when it has rendered a consent judgment it has made an adjudication.
>
> * * *
>
> The court . . . must not merely sign on the line provided by the parties. Even though the decree is predicated on consent of the parties, the judge must not give it perfunctory approval.
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> * * *
>
> Because the consent decree does not merely validate a compromise but, by virtue of its injunctive provisions, reaches into the future and has continuing effect, its terms require more careful scrutiny.
>
> * * *
>
> Like other judicial functions, the decision to approve a consent decree requires ***careful consideration*** and the exercise of discretion.

664 F.2d 435, 440-42 (5th Cir. 1981) (emphasis added) (quoting 1B JAMES WM. MOORE ET AL., MOORE'S FEDERAL PRACTICE ¶ 0.409[5] (2d ed. 1980)); *see Local No. 93, Int'l Ass'n of Firefighters v. City of Cleveland*, 478 U.S. 501, 525 (1986) (recognizing that a consent judgment is a judicial determination or decision); *Citibank, N.A. v. Data Lease Fin. Corp.*, 904 F.2d 1498, 1504 (11th Cir. 1990) (same); *United States v. ITT Cont'l. Baking Co.*, 420 U.S. 223, 236 (1975) ("consent decrees and orders have attributes both of contracts and of judicial decrees"); *Fox v. U.S. Dep't of Hous. & Urban Dev.*, 680 F.2d 315, 319 (3d Cir. 1982) ("consent decrees are judicial acts"); *NLRB v. Brooke Indus. Inc.*, 867 F.2d 434, 435-36 (7th Cir. 1989) (a judge should not automatically sign a consent judgment or accept the form proposed by the parties, but must

consider its potential effects on third parties and on the "integrity and manageability of the judicial process").

Moreover, in *Flex-Foot, Inc. v. CRP Inc.*, the Federal Circuit recognized that consent judgments are judicial decisions, noting that "termination of an infringement suit via a consent decree [is] a decision by the court to which the parties have agreed." 238 F.3d 1362, 1369 (Fed. Cir. 2001); *see Interdynamics, Inc. v. Firma Wolf*, 653 F.2d 93, 96 (3d Cir. 1981) ("a consent decree [in a patent infringement case], although negotiated by the parties, is a judicial act"); *United States v. Swift & Co.*, 286 U.S. 106, 115 (1932) ("We reject the argument for the interveners [in an anti-trust case] that a decree entered upon consent is to be treated as a contract and not as a judicial act.").

In both its brief on appeal to the Federal Circuit, and its earlier submissions to this Court seeking a stay of judgment pending appeal, Sun represented, for example, that "[c]ourts have repeatedly held that consent orders are not 'decision(s)' of the courts." (Gupta Decl. Ex. 3 at 24; D.I. 669.1 at 8-10). But Sun cites no authority that so holds, pointing only to cases that concern the effect or meaning of a "decision *on the merits*." Of course, the term used in Section 3.5 of the Sun License is "decision(s)," not "decision(s) on the merits."

Most of the cases Sun cites concern whether a consent judgment has "issue preclusion" or collateral estoppel effect, since the substantive merits of the case ordinarily have not been actually adjudicated.[10] But Sun ignores that consent judgments do have claim preclusion, or *res judicata* effect as between the parties to the litigation. *Flex-Foot*, 238 F.3d at

[10] These cases include *Arizona v. California*, 530 U.S. 392, 414 (2000); *United States v. Int'l Bldg. Co.*, 345 U.S. 502, 506 (1953); *In re Carrero*, 94 B.R. 306. 310 (Bankr. S.D.N.Y. 1988); *Dunning v. Pacerelli*, 818 P.2d 34, 39 (Wash. Ct. App. 1991); *Am. Mut. Liab. Ins. Co. v. Michigan Mut. Liab. Co.*, 64 Mich. App. 315 (Mich. Ct. App. 1975); *Marquardt v. Fed. Old Line Ins. Co.*, 658 P.2d 20 (1983).

1367-68, 1369; *Citibank*, 904 F.2d at 1503-04. Thus, consent judgments are equivalent to any other "decision" for purposes of precluding relitigation of the parties' substantive claims.

In addition to collateral estoppel cases, Sun also relies on decisions recognizing that a consent judgment ordinarily is not a decision on the merits of the case.[11] While this may be so, it is irrelevant to whether a court rendering a consent judgment makes a "decision" in doing so.

Thus, legal precedent compels the conclusion that "decision(s) enjoining" include consent judgments. Because that meaning has been clearly recognized by many courts, the parties here should be deemed to have embraced it in their contract. *See Hugo Boss Fashions, Inc. v. Fed. Ins. Co.*, 252 F.3d 608, 617-20 (2d Cir. 2001) ("unless they expressly indicate otherwise, contracting parties will be deemed to have incorporated into their agreement usages of key terms that are well-established in the case law"); *CGS Indus., Inc. v. Charter Oak Fire Ins. Co.*, No.10-cv-03186, 2010 WL 4720320, at *4 (E.D.N.Y. 2010) ("If a relevant term is not defined . . . it is to be afforded its ordinary meaning, which may include its usage in federal law").

C. The Extrinsic Evidence Undermines or Fails to Support Sun's Position

The extrinsic evidence that Sun has proffered in this case supports plaintiffs' position -- not Sun's.[12]

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[11] *See Dennis v. County of Fairfax*, 55 F.3d 151, 154 (4th Cir. 1995); *Walker v. U.S. Dept. of Hous. & Urban Dev.*, 912 F.2d 819, 831 (5th Cir. 1990); *Beatrice Foods Co. v. F.T.C.*, 540 F.2d 303, 312 (7th Cir. 1976).

[12] Sun's extrinsic evidence discussed in this brief was before this Court when it denied Sun's motion for a stay of judgment pending appeal. (D.I. 669.1 at 6-8; D.I. 685 at 2). Although the Federal Circuit addressed some of this same evidence in concluding that "decisions enjoining" is ambiguous, that Court did not find that any of Sun's evidence supports Sun's position on the meaning of this phrase (and, indeed, did not reach that issue). (Gupta Decl. Ex. 1 at 11-13, 15).

1. Changes Made to The Parties' Preliminary Terms to Reach Their Final Agreement Refute Sun's Position

Sun's reliance on the parties' January 2009 preliminary term sheet is misplaced. (Travers Decl. Ex. 2; Gupta Decl. Ex. 3 at 31-32; D.I. 669.1 at 7-8). Differences between the Term Sheet provisions and the final Sun License Agreement show that even Sun understood that "decision(s) enjoining" is not limited to "decisions on the merits."

Section 2.C of the term sheet states:	Section 3.5 of the Sun License states:
[I]n the event a Court enters a ***final court decision, finding the '874 patent valid, enforceable and infringed*** by each such At-Risk Launch, Sun agrees that if the Court enjoins such product(s) of each such At-Risk Launch, Sun will not sell its product(s) until the Launch Date and will pay Plaintiffs 60% of [Sun's] gross profits earned with respect to its sales of generic version of Eloxatin . . . . (Travers Decl. Ex. 2, § 2.C, emphasis added).	Should Sun exercise such an option and a Court subsequently enters a decision(s) enjoining each such At-Risk Launch product(s), Sun agrees that Sun will not sell its Generic Equivalent from the time the Court enters an injunction(s) against each such At-Risk Launch Product(s) until the Launch Date. In the event a Court enters a Final Court Decision finding the '874 patent infringed by each and every defendant in the Consolidated Eloxatin Patent Litigation that carried out an At-Risk Launch and does not find the '874 patent invalid or unenforceable, Sun agrees to pay Plaintiffs 60% of [Sun's] Gross Profits earned with respect to sales of Licensed Products . . . . (Travers Decl. Ex. 1, § 3.5).

A comparison of this language discloses that Section 2.C of the term sheet was changed in several significant respects. First, the term sheet states that Sun will "not sell its product(s)" if the "Court enters a final court decision, finding the '874 patent valid, enforceable and infringed" -- *i.e.*, if the court enters a decision on the merits. That language was ***eliminated*** from Section 3.5 of the Sun License, which requires Sun to cease sales if the Court enters "decision(s) enjoining" the at-risk defendants. Thus, as to the phrase "decision(s) enjoining," the

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None of the documents that Sun has recently produced to plaintiffs in discovery support its position on the meaning of "decision(s) enjoining".

parties' final agreement is broader than the term sheet, specifically eliminating the requirement for a decision on the merits.

Second, in the Term Sheet, as shown above, the same sentence that defines Sun's obligation to cease its generic oxaliplatin sales, also requires Sun to pay damages on sales it has made if there is a "final court decision." The final Sun License addresses these two obligations in ***two separate*** sentences: one sentence defining the circumstances in which Sun must cease selling its product, and the other sentence specifying what must occur for Sun to owe damages. The first sentence requires Sun to cease sales upon entry of "decision(s) enjoining" other defendants. The second sentence requires Sun to pay damages under more limited circumstances, namely, if the Court enters a "Final Court Decision" finding that the '874 patent is valid, enforceable and infringed.

2. Plaintiffs' January 2010 Draft Settlement Proposal Is Not Relevant to the Issue Here

Nor does plaintiffs' January 2010 settlement proposal support Sun's position. (Gupta Decl. Ex. 4; *see* Gupta Decl. Ex. 3 at 28-29; D.I. 669.1 at 7). This proposal (made more than seven months after the Sun License) does not change the fundamental point of Section 3.5, namely, that Sun agreed to cease selling its generic oxaliplatin product at the same time all other defendants were enjoined.

[13] Significantly, Sun's definition of "decision(s) enjoining" as limited to fully litigated final decisions on the merits would exclude preliminary injunctions, which plainly are not such decisions. But, a preliminary injunction is the remedy most likely to be sought to enjoin an at-risk launch -- and, indeed, is the remedy plaintiffs sought for this very purpose to terminate the at-risk generic oxaliplatin launches that occurred in August 2009.

3. Sun's Other Proffered Extrinsic Evidence Does Not Support Its Position

Sun also relies on a declaration of its Vice President, Ratnesh Shrivastava, in which Mr. Shrivastava has declared "[i]t was not my intention nor my understanding that the License Agreement would preclude Sun's manufacture and sale of its generic version of oxaliplatin based on the entry of a consent order. . . ." (Gupta Decl. Ex. 6, ¶ 5; D.I. 669.1 at 8). But it is black-letter law that the parties' bilateral, manifest intent controls, not the unilateral, unexpressed intent of one party's representative. *Tom Doherty Assocs. Inc. v. Saban Entm't Inc.*, 869 F. Supp. 1130, 1137, 1139 (S.D.N.Y. 1994) ("The secret intent of the parties is irrelevant to contract interpretation. . . . The unexpressed subjective intent of one party is not binding on the other.") (citing *Porter v. Commercial Cas. Ins. Co.*, 54 N.E.2d 353, 356 (N.Y. 1944)); *Core-Vent Corp. v. Implant Innovations, Inc.*, 53 F.3d 1252, 1256 (Fed. Cir. 1995) ("Since contractual obligations are to be ascertained from objective manifestations of intent, plaintiff's mental reservations are legally irrelevant.") (citation omitted). Thus, Mr. Shrivastava's personal, uncommunicated understanding is of no moment to the contract interpretation issue before this Court.

Finally, Sun relies on plaintiffs' March 26, 2010 letter to this Court requesting that the Court "clarif[y] Sun's obligations." (Gupta Decl. Ex. 5; D.I. 671.3; Gupta Decl. Ex. 3 at 12-13). Although the Federal Circuit cited this letter in its decision, that Court found only that it evidences ambiguity, not that it evidences the meaning of "decision(s) enjoining". And, clearly it does not. In fact, the Federal Circuit expressly recognized that because Sun would "not affirmatively indicate that it would cease generic sales" plaintiffs sought relief from this Court "[b]ecause of the ongoing uncertainty regarding the obligations created by the license agreement terms." (Gupta Decl. Ex. 1 at 6, 7). Clearly, this "uncertainty" concerned Sun's intentions, not plaintiffs' view of Sun's underlying contract obligations. Thus, there is no basis to read plaintiffs' use of the word "clarify" as proof that "decision(s) enjoining" should be limited to decisions "on the merits." Plaintiffs' letter evidences nothing more than their efforts to have this Court resolve their dispute with Sun as to what Sun's obligations are.

II. In the Absence of a Preliminary Injunction, Plaintiffs Will Continue to Suffer Severe Irreparable Harm

In June of 2009, plaintiffs moved the Federal Circuit for a stay pending appeal of this Court's summary judgment of non-infringement in their oxaliplatin patent infringement cases. Because the Federal Circuit granted that motion, the Court necessarily found that plaintiffs would be irreparably harmed by defendants' launch of their generic oxaliplatin products. *Sanofi-Aventis U.S. LLC et al. v. Sandoz, Inc. et al.,* No. 2009-1427 (Fed. Cir. July 10, 2009) (D.I. 681.2) (order granting motion to stay the judgment pending appeal); *see Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 512 (Fed. Cir. 1990).[14]

[14] Plaintiffs' evidence of irreparable harm in support of their motion for a stay is found at D.I. 387 ¶¶ 22-32; D.I. 388 ¶¶ 15-21; and D.I. 389 ¶¶ 34-56.

Thereafter, as this Court is aware, an at-risk generic oxaliplatin launch occurred, beginning in August 2009 and continuing until June 30, 2010, when all defendants were enjoined pursuant to their settlements with plaintiffs.[15]

III. The Balance Of Hardships Favors Preliminary Relief

In contrast to the severe irreparable harm that plaintiffs will suffer in the absence of an injunction, Sun will experience no discernable harm from a short delay of another generic oxaliplatin launch. Sun's experience during the earlier at-risk generic launch that occurred in these cases serves to prove this point.

Sun's generic oxaliplatin is a lyophilized (freeze-dried) product that requires reconstitution by healthcare workers before it can be used. Unlike Sun, a number of the other defendants sell generic oxaliplatin "solution" products, which are sold in a "ready to use" form. Because of inevitable mistakes in reconstituting the lyophilized product, and the risks that its potentially toxic effects present to its handlers, Sun's lyophilized product is heavily disfavored in the marketplace. (Hawthorne Decl. ¶ 21).

As a result, Sun's sales during the earlier at-risk launch were minimal, with the vast majority of customers purchasing the solution product from Sun's generic competitors (Hawthorne Decl. ¶¶ 21-22; Grabowski Decl. ¶¶ 32-34). And, as explained by the head of Sanofi's U.S. oncology business, Mr. Hawthorne, and plaintiffs' expert economist, Dr. Grabowski, if anything, Sun's market share as compared to its generic competition likely will be even smaller in any prospective generic oxaliplatin launch. (Hawthorne Decl. ¶ 23; Grabowski Decl. ¶ 35).[16]

Thus, any potential harm to Sun from a brief delay of another generic oxaliplatin launch is minimal at best, since Sun is unlikely to substantially benefit from such an event. The balance of hardships here thus weighs heavily in favor of plaintiffs, who will suffer substantial and irreparable harm if Sun is not enjoined. (Grabowski Decl. ¶ 36); *Abbott Labs.*, 544 F.3d at 1362 (Fed. Cir. 2008) (the balance of harms tipped strongly in favor of plaintiffs where "preserving the status quo preserve[d] the current market structure" and plaintiffs would "lose much more if this Court did not enjoin [defendant's conduct]"); *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006) (Finding irreparable harm and balance of hardships favored preliminary injunctive relief where defendant's harms were "almost entirely preventable and were the result of its own calculated risk") (internal quotations omitted); *Hamilton Watch Co. v. Benrus Watch Co.*, 206 F.2d 738, 743 (2d Cir. 1953) (balance of hardships weighed in plaintiff's favor where "no substantial harm from the injunction to defendant is perceptible; but the hardship to plaintiff were there no injunction, would be very considerable").

Finally, Sun already has enjoyed a windfall from sales it made during the earlier at-risk launch -- sales that resulted not from any burden assumed by Sun, which had settled with plaintiffs and thus was no longer assuming litigation risk. Rather, Sun enjoyed that windfall solely because other defendants at their own risk and expense had continued to pursue the merits of the oxaliplatin patent infringement cases. Thus, any additional sales by Sun (before it is authorized to sell in August 2012) would be another windfall that clearly goes beyond what the parties' settlement was intended to confer.

IV. The Public Interest Favors the Grant of a Preliminary Injunction

The public interest benefits from enforcement of valid contracts and favors the grant of injunctive relief here. *See Rex Med. L.P. v. Angiotech Pharm. (U.S.), Inc.*, No. 10-cv-08746, 2010 WL 4977775, at *9 (S.D.N.Y. Dec. 1, 2010) ("The public has an interest in seeing that parties oblige by their contractual obligations and are not allowed to skirt such obligations at another's expense"); *Miller v. Cont'l Ins. Co.*, 358 N.E.2d 258, 261 (N.Y. 1976) ("[T]he usual and most important function of courts of justice is rather to maintain and enforce contracts than to enable parties thereto to escape from their obligation..."); *ACE Am. Ins. Co. v. Wachovia Ins. Agency, Inc.*, No. 08-cv-04369, 2008 WL 4630486, at *9 (D.N.J. Oct. 17, 2008) (reasoning that the public interest is furthered by protection of private contractual rights).

V. Plaintiffs Will Post an Appropriate Bond

Plaintiffs are fully prepared to post a bond pursuant to Fed. R. Civ. P. 65(c) to secure Sun against any potential loss. As explained in the accompanying declaration of

plaintiffs' economic expert, Dr. Grabowski, using assumptions that are favorable to Sun, an appropriate amount for a bond is $10.2 million. (Grabowski Bond Decl. ¶¶ 5-11).

CONCLUSION

For the foregoing reasons, plaintiffs' motion for a preliminary injunction should be granted.

Respectfully submitted,

Dated: February 15, 2011

By: _____

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